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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/202,305	03/22/99	MANOLIOS	N 06025.0003

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HM12/1105

EXAMINER

GUPTA, A

ART UNIT	PAPER NUMBER
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1653

17

DATE MAILED: 11/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/202,305

Applicant(s)

Nicholas Manolios

Examiner

Anish Gupta

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) 4,9-11,14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3,6 and 13 is/are rejected.
- 7) ☐ Claim(s) 5, 7-8, 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed, 8-27-01, is acknowledged. Claims 1, 3, 4, 5, 6, 8, 12, and 13 have been amended.

Claims 1, 3-15 are pending in this application.

Election/Restriction

1. Applicant's election with traverse of Group I and the species of SEQ ID. No. 7 in Paper No. 7 and 13 is acknowledged.

Applicants have again made arguments with respect to the restriction. Applicants state that the common technical feature between claims 1-14 and 15 is "peptide according to any one of the claims 1 to 12." The reasoning that the method can be used with a materially different peptide is improper. There need only be a common technical feature and this has been met. Further, it is not clear from the MPEP whether species election practice is applicable to PCT national state application. However, the Administrative Instruction state that if the species have a property or activity in common and share a common structure, then the species meet unity of invention.

The MPEP states if an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered. If there is no link remaining, an objection of lack of unity may be raised. Similar considerations apply in the case of a genus/species or combination/subcombination situation. See MPEP 1849. As indicated in the previous office action and the action below, the claims do not avoid prior art. Art has been cited against the claims and thus objection of lack of unity may be raised, as authorized by the MPEP. Further, with respect to the species arguments. It should be noted that the species do not share a common property. Applicants have stated indicated in their response that the peptide disclosed in Mozes et al., even though it meets all of the structural limitation, does not have the desired function. Thus, the peptides lack a common property. With respect to structure, the peptides are generic and do not share a common core. Note that both X, and Z are variable to many amino acid substitutions. Thus, the peptides do not share a common structure.

The election is maintained and made final.

Applicants have requested some clarification of the examination of species. Applicants have also stated that claims 1, 9-11, and 14 should be rejoined and considered since the examiner has already searched the elected species. Further, claim 4 should be examined since it reads on claim 1 wherein Z is Arg or Lys and encompass the sequence that have already been searched.

Under species election, the procedure for examination of the elected species as follows. The claims are examined to the extent they read on the elected species. If the elected species is free of prior art, that species is indicated as being allowable and the search is extended to the next disclosed species. The same procedure is followed for all of the species disclosed to determine patentability. A search is stopped once art is found on one of the species and applied to the claims. However if prior art is not found that anticipates or renders obvious the any of the disclosed species, the search is extended to the Markush - type claim. Once art is found on the generic claim, the claim is (again) rejected and claims to the non elected species are held withdrawn from consideration. A claim can be held, even though the elected species may have read on the said claim, as non-elected. In essence, the claims are examined with respect to the species and allowability is determined for the species.

Thus, as indicated in the previous office action, allowability was established for the species corresponding to SEQ ID NO: 6-15 and 17-26. The search was extended in the Markush group and a peptide was found that read on generic claim 1. Although claims 4, 9-11 and 14 were examined with respect to SEQ ID. No 6-15 and 17-26, they were held as non elected since they did not read on the elected species found in the prior art. Note that under species examination a claim can be held, even though the elected species may have read on the said claim, as non-elected.

As stated in the previous office action, claims 1-3, 6, 13 have been examined to the extent they read on the prior art. Claims drawn to the nonelected species, claims 4, 9, 10-11, 14-15 are held withdrawn from further consideration.

Claim Objections

2. The objection of claims 5-7, 12-13 are under 37 C.F.R. § 1.75 as being in improper form because a multiple dependent claim is hereby withdrawn.
3. The objection of claim 8 for informalities is hereby withdrawn.

Claim Rejections - 35 USC § 112

4. The rejection of claim 1-3, 5-8, 12 and 13 under 35 U.S.C. 112, second paragraph, is hereby withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 6, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mozes et al. as stated in the previous office action and the reasons set forth below.

The claims are drawn hydrophobic peptide and therapeutic composition thereof of which the below peptide are within the scope of the present claims.

Applicants, in the response of 8-27-01, argue that Mozes et al. does not suggest that the peptides interfere with T-cell antigen receptor assembly or function.; the peptides of the reference are drawn peptides that comprise T-cell epitomes that bind to MHC gene products; thus the peptides of the reference do not teach the claimed invention is unpersuasive.

The claimed language of "T-cell antigen receptor (TCR) function" is an intended use limitation and intended use or field of use. However, intended use limitation and intended use or field of use for the invention generally will not limit the scope of a claim. Moreover, where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. In re Best, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, *supra*.

Rejection is maintained.

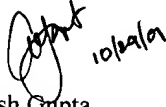
6. Claims 5, 7-8, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Anish Gupta


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